UNIVERSITY OF MICHIGAN HEALTH
MICHIGAN MEDICINE

COVID-19: Patient Education Before Casirivimab and Imdevimab or Bamlanivimab and Etesevimab or Sotrovimab (FDA EUA)

Fact Sheet for Patients, Parents and Caregivers: Emergency Use Authorization (EUA) Of [Casirivimab and Imdevimab], [Bamlanivimab and Etesevimab], or [Sotrovimab] For Coronavirus Disease 2019 (Covid-19)

You are receiving one of the following medications for the treatment of coronavirus disease 2019 (COVID-19): casirivimab/imdevimab, bamlanivimab/etesevimab, or sotrovimab (referred to collectively as **COVID mAb**). This Fact Sheet contains information to help you understand the potential risks and benefits of taking COVID mAb which you may receive.

Receiving COVID mAb may help to:

- Treat COVID-19 in certain people
- Prevent COVID-19 in certain people who:
  - Have been exposed to someone infected with SARS-cov-2
    Or
  - Are at high risk of an exposure because of where they live, such as nursing homes or prisons.

Read this Fact Sheet for information about COVID mAb. Talk to your healthcare provider if you have questions. It is your choice to receive COVID mAb or stop at any time.

What is COVID-19?

COVID-19 is caused by a virus called a coronavirus. People can get COVID-19 through contact with another person who has the virus.

COVID-19 illnesses have ranged from very mild (including some with no reported symptoms) to severe, including illness resulting in death. While information so far suggests that most COVID-19 illness is mild, serious illness can occur and may cause some of your other medical conditions to become worse. People of all ages with severe, long-lasting (chronic) medical conditions like heart disease, lung disease, and diabetes, for example, seem to be at higher risk of being hospitalized for COVID-19.

What are the symptoms of COVID-19?

The symptoms of COVID-19 include fever, cough, and shortness of breath, which may appear 2 to 14 days after exposure. Serious illness including breathing problems can occur and may cause your other medical conditions to become worse.

What are COVID mAb?

COVID mAb are investigational medicines used together in adults and adolescents (12 years of age and older who weigh at least 88 pounds (40 kg)) who are at high risk for developing severe COVID-19, including hospitalization or death for:

- **Treatment of mild to moderate symptoms of COVID-19**

or

- **Post-exposure prophylaxis (prevention) of COVID-19 in people who are** (casirivimab/imdevimab and bamlanivimab/etesevimab only):
    1. Not fully vaccinated against COVID-19 (Individuals are considered **fully vaccinated** 2 weeks after their second dose in a 2-dose series

[such as the Pfizer or Moderna vaccines], or 2 weeks after a single-dose dose vaccine [such as Johnson & Johnson's Janssen vaccine]),

or

2. Are not expected to build up enough of an immune response to the complete COVID-19 vaccination (for example, someone with immunocompromising conditions, including someone who is taking immunosuppressive medications)

and

- Have been exposed to someone who is infected with SARS-CoV-2. **Close contact** with someone who is infected with SARS-CoV-2 is defined as being within 6 feet for a total of 15 minutes or more, providing care at home to someone who is sick, having direct physical contact with the person (hugging or kissing, for example), sharing eating or drinking utensils, or being exposed to respiratory droplets from an infected person (sneezing or coughing, for example). For additional details, go to https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html,

or

- Someone who is at high risk of being exposed to someone who is infected with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (for example, nursing homes, prisons).

COVID mAb are investigational because they are still being studied.

There is limited information known about the safety or effectiveness of using COVID mAb to treatment or prevention of COVID-19. COVID mAB are not authorized for pre-exposure prophylaxis for prevention of COVID-19. For more

information on EUA, see the "What is an Emergency Use Authorization (EUA)?" section at the end of this Fact Sheet.

What should I tell my health care provider before I receive COVID mAbs?

Tell your healthcare provider about all of your medical conditions, including if you:

- Have any allergies
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Have any serious illnesses
- Are taking any medications (prescription, over-the-counter, vitamins, and herbal products)

How will I receive COVID mAb?

- Each COVID mAb contains two investigational medicines given together as a single intravenous infusion (through a vein) for at least 30 minutes.
- You will receive one dose of COVID mAb by intravenous infusion.

What are the important possible side effects of COVID mAb?

Possible side effects of COVID mAb are:

- **Allergic reactions.** Allergic reactions can happen during and after infusion with COVID mAb. Tell your healthcare provider right away if you get any of the following signs and symptoms of allergic reactions:
  - Fever
  - Chills
  - Nausea
  - Headache
  - Shortness of breath
  - Low or high blood pressure
  - Rapid or slow heart rate
  - Chest discomfort or pain
  - Weakness
  - Confusion

- Feeling tired
- Wheezing
- Swelling of your lips, face, or throat
- Rash including hives
- Itching
- Muscle aches
- Dizziness
- Sweating

These reactions may be severe or life threatening.

- **Worsening symptoms after treatment:** You may experience new or worsening symptoms after infusion, including:
  - Fever
  - Difficulty breathing
  - Rapid or slow heart rate
  - Tiredness
  - Weakness or confusion

  If these occur, contact your healthcare provider or seek immediate medical attention as some of these symptoms have required hospitalization. It is unknown if these symptoms are related to the treatment or are due to the progression of COVID-19.

The side effects of getting any medicine by vein may include:

- Brief pain
- Bleeding
- Bruising of the skin
- Soreness
- Swelling
- Possible infection at the infusion site

These are not all the possible side effects of COVID mAb. Not a lot of people have been given COVID mAb. Serious and unexpected side effects may happen COVID mAb are still being studied so it is possible that all of the risks are not known at this time.

It is possible that COVID mAb could interfere with your body's own ability to fight off a future infection of SARS-CoV-2. Similarly, COVID mAb may reduce your body's immune response to a vaccine for SARS-CoV-2. Specific studies have not been conducted to address these possible risks. Talk to your healthcare provider if you have any questions.

What other treatment choices are there?

Like COVID mAb, FDA may allow for the emergency use of other medicines to treat people with COVID-19. Go to https://www.covid19treatmentguidelines.nih.gov/ for information on other medicines used to treat people with COVID-19.

It is your choice to be treated or not to be treated with COVID mAb. Should you decide not to receive COVID mAb or stop it at any time, it will not change your standard medical care.

What if I am pregnant or breastfeeding?

There is limited experience treating pregnant women or breastfeeding mothers with COVID mAb. For a mother and unborn baby, the benefit of receiving COVID mAb may be greater than the risk from the treatment. If you are pregnant or breastfeeding, discuss your options and specific situation with your healthcare provider.

How do I report side effects with COVID mAb?

Tell your healthcare provider right away if you have any side effect that bothers you or does not go away.
Report side effects to FDA MedWatch at www.fda.gov/medwatch or call 1-800-FDA-1088 or call 1-844-734-6643.

How can I learn more?

- Ask your health care provider.
- For casirivimab and imdevimab visit www.REGENCOV2.com
- For bamlanivimab and etesevimab visit www.BAMandETE.com
- For sotrovimab visit www.sotrovimab.com
- Visit https://www.covid19treatmentguidelines.nih.gov/
- Contact your local or state public health department.

What is an Emergency Use Authorization (EUA)?

The United States FDA has made COVID mAbs available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Service (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

COVID mAbs have not undergone the same type of review as an FDA-approved or cleared product. The FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that it is reasonable to believe that the product meets certain criteria for safety, performance, and labeling and may be effective in treatment of patients during the COVID-19 pandemic. All of these criteria must be met to

allow for the product to be used in the treatment of patients during the COVID-19 pandemic.

The EUA for COVID mAbs is in effect for the duration of the COVID-19 declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

To view current fact sheets, and learn more about COVID-19 mABs visit:

- Emergency Use Authorization (US Food and Drug Administration webpage) https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs
- "FDA Combating COVID-19 With Therapeutics" (article): https://www.fda.gov/media/136832/download

Casirivimab and Imdevimab: Manufactured by: Regeneron Pharmaceuticals, Inc. 777 Old Saw Mill River Road Tarrytown, NY 10591-6707

Bamlanivimab and etesevimab: Eli Lilly and Company, Indianapolis, IN 46285, USA

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Sotrovimab: Manufactured by GlaxoSmithKline LLC, Philadelphia, PA 19112

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